

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Marc Feldmann and Ravinder N. Maini

Serial No. : 09/754,004 Examiner: P. Gambel

Filed : January 3, 2001 Group Art Unit: 1644

For : TNF α ANTAGONISTS AND METHOTREXATE IN THE
TREATMENT OF TNF-MEDIATED DISEASE1185 Avenue of the Americas
New York, New York 10036
February 17, 2005Commissioner for Patents
P.O. Box /1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents which are listed on the attached Form PTO-1449 (**EXHIBIT A**). Copies of the documents listed below as items 1 and 2 are attached hereto as **EXHIBITS 1** and **2**:

1. St. Clair, E. W., et al., "Combination of Infliximab and Methotrexate Therapy for Early Rheumatoid Arthritis", Arthritis & Rheumatism, 50(11):3432-3443 (2004) (**EXHIBIT 1**); and
2. Klareskog, L., et al., "Therapeutic effect of the combination of etanercept and methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomised

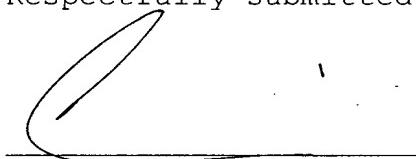
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controlled trial", The Lancet, 363:675-681 (2004)
(EXHIBIT 2).

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

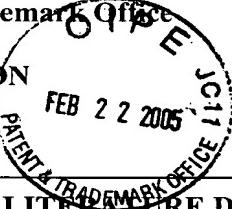

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Alan J. Morrison
Reg. No. 37,399

2/17/05
Date

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Application Number	09/754,004	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Filing Date	January 3, 2001	
				First Named Inventor	Marc Feldmann	
				Art Unit	1644	
				Examiner Name	P. Gambel	
				Attorney Docket No.	1455/65019-DA-PCT-US/JPW/AJM/CY	
NON PATENT LITERATURE DOCUMENTS						
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
		ST. CLAIR, E. W., et al., "Combination of Infliximab and Methotrexate Therapy for Early Rheumatoid Arthritis", <u>Arthritis & Rheumatism</u> , 50(11):3432-3443 (2004)				
		KLARESKOG, L., et al., "Therapeutic effect of the combination of etanercept and methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomised controlled trial", <u>The Lancet</u> , 363:675-681 (2004)				
EXAMINER SIGNATURE		DATE CONSIDERED				
*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional).						
² Applicant is to place a checkmark here if English language Translation is attached.						

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Exhibit A